

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
 v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)
)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8216

Bartle, C.J.

July 2, 2009

Nancy K. Sloane ("Ms. Sloane" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Ms. Sloane's spouse, Jeffrey G. Sloane, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Gregory R. Boxberger, M.D. Based on an echocardiogram dated February 23, 2001, Dr. Boxberger attested in Part II of Ms. Sloane's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50%-60%. Based on such findings, claimant would

3(...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

be entitled to Matrix A-1, Level II benefits in the amount of \$556,216.⁴

In the report of claimant's echocardiogram, Patrick C. Hsu, M.D., F.A.C.C., the reviewing cardiologist, stated that "moderate mitral regurgitation is present." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Hsu also measured claimant's left atrial dimension as 4.01 cm in the antero-posterior dimension and stated that claimant's "left atrial size is normal." The Settlement Agreement, however, defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Dr. Hsu also stated that claimant's "[l]eft ventricular ejection fraction is estimated at

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension and a reduced ejection fraction, which are among the complicating factors needed to qualify for a Level II claim, the only remaining issue is claimant's level of mitral regurgitation.

55%." An ejection fraction is considered reduced for a mitral valve claim if it is measured as less than or equal to 60%. See id.

In February 2004, the Trust forwarded the claim for review to Issam M. Mikati, M.D., one of its auditing cardiologists. In audit, Dr. Mikati concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. According to Dr. Mikati: "There was no tracing on tape of MR jet. I traced several jets[.] The maximum area I got was 2.2 cm². LA area was 23 cm². Ratio is less than 20%. MR is mild."

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Sloane's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵

In contest, claimant submitted the declarations of Dr. Boxberger, as well as Roger W. Evans, M.D., and Dan A. Francisco, M.D. Dr. Boxberger stated that he reviewed the echocardiogram a

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Sloane's claim.

second time and concluded that claimant had "'moderate' mitral valve regurgitation with a RJA/LAA ratio of 25%." Dr. Evans also found that claimant's RJA/LAA ratio was 25% and was "best seen in the apical 4-chamber view." Dr. Francisco stated that claimant had "'moderate' mitral valve regurgitation with a RJA/LAA ratio of 23%." Claimant argued that the issue in this case is not whether the echocardiogram demonstrates moderate mitral regurgitation, but whether Dr. Boxberger had a reasonable medical basis to come to that conclusion. Claimant maintained that a reasonable medical basis exists based on the declarations of Drs. Boxberger, Evans and Francisco, as well as the findings of the original interpreting cardiologist.

The Trust then issued a final post-audit determination, again denying Ms. Sloane's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Sloane's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5241 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 4, 2005, and Claimant was granted permission to submit a sur-reply dated September 1, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue,

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposition positions" is proper. Id.

we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Sloane incorporates the arguments she raised in contest and argues further that the Trust failed to consider the expected inter-reader variability in the measurement of mitral regurgitation. In response, the Trust counters that Drs. Boxberger, Evans and Francisco are frequent Green Form filers and/or experts on behalf of claimants in fen-phen litigation, and therefore their credibility should be questioned. The Trust argues further that Dr. Boxberger merely restates his previous findings in his declaration and that Drs. Evans and Francisco merely opine that claimant has moderate mitral regurgitation without addressing the specific audit findings of Dr. Mikati. The Trust also contends that inter-reader variability does not account for the variance between the findings of Dr. Boxberger and Dr. Mikati. In the sur-reply, claimant asserts that the Trust misinterprets the medical literature relative to inter-reader variability.

Dr. Vigilante reviewed claimant's February 23, 2001 echocardiogram and concluded that there was a reasonable medical

basis for the attesting physician's finding of moderate mitral regurgitation.⁷ In particular, Dr. Vigilante determined that:

Visually, a small jet of mitral regurgitation was seen in the parasternal long axis view. The mitral regurgitant jet was closely evaluated in the apical four chamber and apical two chamber views. The mitral regurgitation appeared most impressive in the apical two chamber view. Visually, the mitral regurgitation appeared moderate in severity in the apical two chamber view. I digitized those cardiac cycles in the apical four chamber and apical two chamber views in which the mitral regurgitant jet appeared most impressive. I electronically traced the RJA and LAA in several cardiac cycles. In the apical two chamber view, the RJA/LAA ratio was 21 to 22%. The RJA/LAA ratio was 17 to 18% in the apical four chamber view. I am unable to determine how the Auditing Cardiologist calculated the maximum RJA measurement to be 2.2 cm². I determined the RJA to be much larger than this value. The apical two chamber view clearly demonstrated a more impressive mitral regurgitation jet than the apical four chamber view. I disagree with Dr. Evans regarding the view in which the mitral regurgitation was best seen. My assessment of the degree of mitral regurgitation correlates with that of Dr. Hsu noted in the original echocardiogram report.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician reviewed

7. Dr. Vigilante also found that claimant's "left atrium measured 4.1 cm in the antero-posterior dimension and 5.4 cm in the supero-inferior dimension." Dr. Vigilante stated that claimant's "left ventricular ejection fraction was 65%." As noted above, however, the Trust does not contest that claimant has a complicating factor needed to qualify for a Level II claim.

claimant's echocardiogram and found that claimant had moderate mitral regurgitation. Although the Trust contested the attesting physician's conclusion, Dr. Vigilante confirmed the attesting physician's finding of moderate mitral regurgitation.⁸ Specifically, Dr. Vigilante stated that "there is a reasonable medical basis for the Attesting Physician's answer . . . the echocardiogram of February 23, 2001 demonstrated moderate mitral regurgitation in the apical two chamber view . . . This degree of mitral regurgitation was present both visually and with measurements and calculation of the RJA/LAA ratio in the apical two chamber view."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Vigilante measured claimant's mitral valve regurgitation as 21 to 22% in the apical two chamber view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim. Accordingly, we need not address claimant's remaining arguments.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1,

8. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Level II benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Ms. Sloane and her spouse for Matrix Benefits.